

REMARKS/ARGUMENTS

The above-identified patent application has been reviewed in light of the Examiner's Action dated July 31, 2008. Claims 1, 3-11, 14,15, 17-21, 23-27, and 29-31 have been amended and claim 32 has been canceled, without intended to abandon or to dedicate to the public any patentable subject matter. Accordingly, claims 1-31 are now pending. As set forth herein, reconsideration and withdrawal of the objections to and rejections of the claims are respectfully requested.

Claims 23-24 and 31 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In the amendments set forth above, claims 23-24 and 31 have been amended such that the basis for this rejection has been removed. In particular, amendments have been entered that, while not altering the scope of the claims, are believed to clarify those claims.

Claims 1-23, 25, and 29-31 and 20-28 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,270,479 to Bergens et al. In addition, claim 24 stands rejected under 35 U.S.C. § 103 as being unpatentable over Bergens et al. in view of U.S. Patent No. 4,958,622 to Selenke. Claims 26-27 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bergens et al. in view of U.S. Patent No. 5,634,906 to Haber et al.. Finally, claim 28 stands rejected under 35 U.S.C. § 103 as being unpatentable over Bergens et al. in view of U.S. Patent No. 5,042,977 to Bechtold et al. In order for a rejection under 35 U.S.C. § 102 to be proper, each and every element as set forth in a claim must be found, either expressly or inherently described, in a single prior art reference. (MPEP § 2131.) In order to establish a prima facie case of obviousness under § 103, there must be some suggestion or motivation to modify the reference or to combine the reference teachings, there must be a reasonable expectation of success, and the prior art reference or references must teach of suggest all the claim limitations (MPEP § 2143.) However, all of the claim elements cannot be found in the cited references, whether those references are considered alone or in combination. In particular, the cited references do not disclose an inner housing with radially flexible tags that is moveable between three positions as claimed. Accordingly, reconsideration and withdrawal of the rejections of the claims as anticipated by or obvious in view of the cited references are respectfully requested.

Bergens et al. describes a device with elements 132 and 133 in communication with a barrel and legs 143 in communication with a plunger. However, the Bergens device does not comprise an inner housing intermediate the outer housing and the barrel and plunger, and therefore does not operate in the manner defined by claim 1 of the present application. Moreover, Bergens does not disclose an inner housing with radially flexible tags that is moveable between three positions as claimed.

The Examiner does not clearly specify which component of Bergens et al. is believed to equate to the claimed inner housing other than saying "e.g. 130". The component 130 is a carrier for the medicament container 120. Carrier 130 is not moveable by an energy source between the three positions required by claim 1 of the present application. In particular, carrier 130 does not communicate at all with the plunger 126 and can therefore not operate in the three stage manner outlined in claim 1.

When triggered, the drive spring 141 of the Bergens device acts on an injection head 142 which moves a container barrel by pushing a sleeve-like syringe plunger 151 into contact with a flange 124. As the container moves forward the needle is exposed and penetrates the injection site. When the container has reached the end of its travel, plunger guide 154 continues to move forward and causes legs 143 to compress by contact with tapered surface 161. Injection head 142 then pushes plunger 126 through the barrel to expel the medicament. When the plunger reaches the end of the barrel, the legs of 143 have reached an expansion cavity 163 and flex away from contact with the plunger 126. The container 120 (and its carrier 130) then retracts under the influence of return spring 134.

While the Bergens device describes elements that communicate with the barrel and plunger, these elements do not form part of a single component, namely an inner housing intermediate the outer housing and the barrel and plunger, as required by claim 1 of the present application. In addition, "tags" 132 and 133 do not flex radially to allow the barrel or plunger to move but merely hold the container 120.

The sleeve shaped syringe plunger, part 151, is perhaps the closest equivalent to the inner housing of the present invention. However, plunger part 151 is not "intermediate the outer

housing and the barrel and plunger” as required by claim 1. Furthermore, neither the flexible insert 132 and 133, nor legs 143 comprise part of the syringe plunger part 151.

The above arguments demonstrate that the Bergens device does not anticipate claim 1 of the present application since it does not disclose an inner housing as defined by claim 1. The Bergens device does not operate by moving said inner housing between the three positions described in claim 1. These arguments apply equally to independent claims 29 and 30. Since it has been shown that claim 1 is novel over Bergens et al., it follows that dependent claims 2 to 23 and 25 are also novel in light of Bergens et al.

The Examiner considers claim 24 to be unpatentable over Bergens et al. in view of Selenke. As has been shown above, Bergens et al. Does not disclose the features of claim 1, which claim 24 is ultimately dependent upon. Furthermore, Selenke does not describe a floating rivet intermediate the needle cover and the protective rubber sheath, as required by claim 24. Selenke describes a screw cap that fits over a needle having a needle sheath, but the cap is merely screw threaded around the needle. Claim 24 of the present application is dependent upon claim 23 which requires that the needle cover includes means for pulling the protective rubber sheath from the needle. The cap described in Selenke does not include these means. These means are also not disclosed by Bergens. Therefore, claim 24 is not obvious in light of Bergens et al. and Selenke and the rejection of claim 24 should be reconsidered and withdrawn.

The Examiner has also considered claims 26 and 27 as obvious in light of Bergens et al. and Haber et al. Again, claims 26 and 27 are ultimately dependent upon claim 1, the features which have already been shown not to be anticipated by Bergens et al. In any case, Haber et al. does not disclose any features of claims 26 or 27 that would render them obvious.

Haber describes a device having a cartridge housing 26 that is slideable within an outer spring sleeve 68. In contrast with claims 26 and 27, however, no components move intermediate of the two windows, 72 and 30, to obscure the inner window 30 from the user’s view. For these reasons, claims 26 and 27 are therefore not obvious in light of Bergens et al. and Haber et al. and the rejections of claims 26 and 27 should be reconsidered and withdrawn.

Application No. 10/597,379


The Examiner also believes that the features of claim 28 are obvious in light of Bergens et al. and Bechtold et al. Claim 28 is directly dependent upon claim 1, and so the above argument concerning Bergens applies.

Bechtold describes a device wherein a blind user can set the required dose by counting the number of audible clicks when rotating a dial. Bechtold does not describe means for emitting an audible and/or physical indication to a user that the injection is complete, as required by claim 28. There is no motivation, contrary to the Examiner's suggestion, to apply the dosage clicking means of Bechtold to one of the spring mechanisms of Bergens et al. to "ensure a patient is aware when a dosage cycle has completed". It follows therefore, that claim 28 is not rendered unpatentable by Bergens et al. in view of Bechtold et al. and that the rejection of claim 28 should be reconsidered and withdrawn.

It is believed that the arguments stated above overcome all of the objections raised in the Office Action and that all the claims are novel and non-obvious over the prior art cited by the Examiner. The application now appearing in form for allowance, early notification of same is respectfully requested. The Examiner is invited to contact the undersigned by telephone if doing so would be of assistance.

Respectfully submitted,

SHERIDAN ROSS P.C.

By: 
Bradley M. Knepper
Registration No. 44,189
1560 Broadway, Suite 1200
Denver, Colorado 80202-5141
(303) 863-9700

Date: October 30, 2008